

**SUMMARY OF SAFETY AND
EFFECTIVENESS DATA (SSED)**

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I. GENERAL INFORMATION

Device Generic Name:	Injectable Dermal Filler
Device Trade Name:	Restylane® Injectable Gel
Sponsor's Name and Address:	Medicis Aesthetics Holdings, Inc. 8125 North Hayden Road Scottsdale, AZ 85258
Date of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P040024
Date of Notice of Approval To the Applicant:	March 25, 2005

II. INDICATIONS FOR USE

Restylane is indicated for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

III. DEVICE DESCRIPTION

Restylane consists of stabilized, hyaluronic acid (HA) generated by streptococcal bacteria and formulated to a concentration of 20 mg/ml, suspended in a physiological buffer pH 7. Restylane is a transparent, viscous and sterile gel, supplied in a disposable glass syringe. Each syringe contains 0.4 or 0.7 ml gel. The contents of the syringe are sterile. The syringe is equipped with a plunger stopper, finger grip and plunger rod. The syringe is packed in a blister together with a sterile 30 G needle.

The HA has a molecular weight of about 1 million and is stabilized by adding a minimum amount of BDDE to allow formation of a 3-dimensional HA molecular network (gel). The chemical stabilizing process does not change the polyanionic character of the polysaccharide chain. Only about 1% of the polysaccharide has been stabilized.

IV. Center for Devices and Radiological Health (CDRH) DECISION

The application includes by reference the data in PMA P020023 and related supplements for Restylane® Injectable Gel Submitted by Q-Med AB and approved on December 12, 2003. Q-Med AB has authorized Medicis Aesthetics, Inc. to incorporate the information contained in its approved PMA and related supplements. The applicant's manufacturing facility was inspected and found to be in compliance with the Quality System Regulation (21 CFR 820). CDRH issued the approval order to Medicis Aesthetics Holdings, Inc on

March 25, 2005. For data supporting the approval decision refer to the attached summary of safety and effectiveness data for P020023.

V. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.